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JG-RP-4796/500561.20065

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Claudia Cherney STEWART	Group: 1617
Serial No.:	09/330,629	Examiner: S. HUI
Filing Date:	June 11, 1999	Customer No: 026418
For:	METHOD OF HIV AND HPV PROPHYLAXIS	

Commissioner for Patents
Washington, D. C. 20231

RESPONSE

S i r:

This is in response to the Office Action mailed October 10, 2001.

Reconsideration and withdrawal of the rejection of claims 1-14 as being unpatentable over the Dori WO '140 in view of Cooper et al. '359 are requested. The examiner asserts that Dori teaches a method for treating viral infection and decreasing viral titer broadly by topically administering metallo-organic cobalt compounds, including Compound No. 96 which is a compound of the present claims. The examiner recognizes that Dori does not disclose a method for Prophylaxis for Human Immunodeficiency Virus (HIV) by the topical administration of this or any other compound. In addition, Dori does not disclose the method of using a condom as an applicator for the topical administration.

The examiner relies on Cooper et al. as teaching a method of topical administration of a medical agent by applicators which may include a condom.

The examiner concludes that one of ordinary skill in the art would have been motivated to utilize the present compounds for HIV prophylaxis because the compounds of Dori are known to be effective in treating viral infections." However, it is submitted that this is an improper characterization of the disclosure of Dori and requires a leap of technical logic for which there is no basis.

It has been pointed out, Dori is solely directed to the therapeutic use of the metallo-organic cobalt compounds shown therein to treat subjects with viral infections. There is absolutely nothing in Dori which in any way suggests that the compound shown therein, much less, Compound 96, has any prophylaxis effect with respect to preventing the infection prior to a virus infecting the actual cell. The concept of therapeutic treatment with respect to a patent who already has a disease is significantly different from the concept of treatment for the purpose of prophylaxis before a patient or subject has a disease.

From the data shown in the present application, it is clear that the present discovery shows a prophylactic effect by virtue of the use of the compounds recited in the present claims. Thus, as shown in Example 2, stock solutions of viruses were treated for one hour with an equal volume of medium containing Compound 96. Thereafter, as discussed at page 13, these virus drug solutions were diluted a thousand fold. These diluted solutions were then mixed with an equal volume of PBMC cells to achieve a final

dilution of virus and drug of 1 to 4000. This resulted in a final virus concentration of 1 ng/ml.

The infected cultures were incubated thereafter for four days and then assayed for infection. The result showed that the T cell-tropic (NL-HX) and macrophage-tropic (NL-HX-ADA) were completely inactivated even at the lowest concentration of drug tested. Clearly, this demonstrates the prophylaxis ability of the drug and the uniqueness of the method of the present invention.

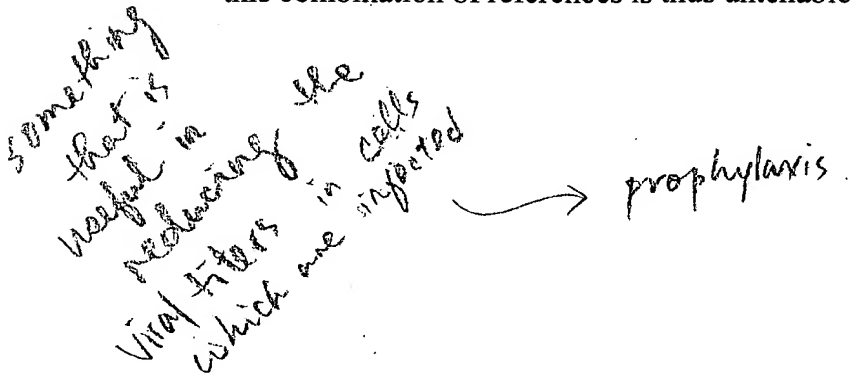
Dori contains no information which the skilled artisan could in any way conceive that a prophylactic effect has taken place. Thus, in Example 1, drug solutions were mixed with HSV-one suspensions in a 1 to 1 ratio and then this mixture was incubated for 30 minutes. After the inhibition, aliquots were overlaid unto triplicate confluent cell monolayers. There was no significant dilution as described in Example 2 of the present application.

After 30 minutes of incubation, the inoculum medium containing the drug concentration was added to the monolayers. In essence, the monolayers had already been infected with the virus. The purpose of this experiment was to show the effect of the drug treatment after the cell had been infected. There was certainly no indication or suggestion that any kind of prophylactic effect might be possible, much less, determined by this procedure. As is clearly pointed out at Column 3, beginning at line 8, the inventive compounds of the Dori patent "exhibit significant activity as anti-viral agents and can be used for treating viral infections. This means the disclosure is clearly directed to and the skilled artisan would understand it to be directed to, the treatment of persons being

infected with the virus. There is absolutely no suggestion that the compounds can be used for a prophylactic effect, i.e., the treatment of persons who are not infected with the virus but in an effort to hinder or prevent that person who is exposed to the virus.

The examiner has cited no portion in this reference which would support the assertion that one would reasonably expect Compound 96 to be useful in lowering the incidence of "viral infections" in a group of subjects. The only data and the entire thrust of the reference is that the compound can reduce the viral titers of cells (and persons) who already have been infected with the virus. The assertion that the reference shows Compound 96 as effectively lowering the inter-cellular viral titer is not relevant to the prophylaxis effect as such. Rather, it is only relevant to the reduction of the vital titer as disclosed in the reference with cells that have already been infected with the virus.

The Cooper et al. reference contains no information which makes Dori more relevant to the present invention as claimed. Whether or not Cooper et al. discloses the use of a condom as an applicator is not material to making Dori more relevant. Thus, even assuming that the examiner's characterization of Cooper et al. is correct with regard to its disclosing a condom as an applicator, one skilled in the art would find nothing in Cooper et al. which would lead them to conclude that the compound and procedures disclosed in Dori could be used in any way as prophylactic measures. The rejection on this combination of references is thus untenable and should be withdrawn.



In view of the foregoing, it is submitted that this application is now in condition for allowance and favorable reconsideration and prompt notice of allowance are earnestly solicited.

Respectfully submitted,
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By: _____
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